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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,506	12/21/2001	Hanuman B. Jampani	ETH-1601 (J&J 3.0-071)	4582
1815	7590	03/23/2004	EXAMINER	
SELITTO, BEHR & KIM 203 MAIN STREET METUCHEN, NJ 08840-2727			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/029,506

Applicant(s)

JAMPANI ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/17/03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, corrected drawings, amendment to the specification, amendment to the claims and supplemental IDS, all filed 11/17/03. Claims 1-45 are pending.

1. The indicated allowability of claims 25 and 40-43 is withdrawn in view of the new rejection below.

#### ***Claim Rejections - 35 USC § 102***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-11, 17-24, 27-33 and 39-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenthal et al. (EP 0 562 864).

Rosenthal discloses a wound dressing material or implant material that comprises a matrix of bioabsorbable biopolymer material and a substructure of bioabsorbable biopolymer films which is embedded in the matrix structure and where one or more active agents are incorporated separately into the matrix and/or the substructure in order to provide controlled or phasic release of the active agent into the wounds (abstract and column 3, lines 22-34).

Rosenthal teaches that polyglycolic acid, structural proteins such as collagen, elastin and fibronectin and polysaccharides are bioabsorbable materials that are used to fabricate the porous wound dressing or implants (column 1, lines 6-22). Anti-microbial is an example of active agent incorporated to control infection in the heteromorphic wound dressing sponge of Rosenthal (column 3, lines 36 and 37). In example 3, a two-component heteromorphic sponge wound dressing comprising chlorhexidine gluconate in both the sponge matrix and the substructure is

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prepared and in this case, a variation of the preparatory method calls for the use of oxidized regenerated cellulose fabric precoated with hyaluronic acid (column 7, line 56 to column 8 line 6).

In Rosenthal, the substructure of polyglycolic acid film is the enclosing film and since the anionic carrier of oxidized regenerated cellulose interacts with the active anti-microbial agent that satisfies the limitation of cationic agent, the interaction would inherently be ionic. The instant method is directed to administering a pharmaceutical active agent and the reference applies the wound dressing sponge to a wound and the rate would inherently depend on the rate of biodegradability of the substructure. Thus the teachings of Rosenthal meet the limitation of the claims.

Applicants' argument that the prior art does not disclose an enclosing means is not persuasive because the prior art disclosing an enclosing means such as that recited in the instant case. The claims recite "enclosing means for enclosing said carrier/active agent combination, said enclosing means including ....". The feature of an envelope upon which applicants base the argument is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The envelope feature appears not to be so disclosed by the instant disclosure.

#### ***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 12-16 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal et al. (EP 0 562 864).

Rosenthal clearly teaches the porous biocompatible device of the instant invention except that Rosenthal fails to give the size of the pores. However, the pores should have certain sizes and since Rosenthal is silent on the size of the pore, it would appear that the prior art teaches all pore sizes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a porous wound dressing sponge according to the teaching of Rosenthal. One having ordinary skill in the art would have been motivated to prepare the porous wound dressing sponge having pore sizes that would permit the effective release of the anti-microbial agent. There is no showing demonstrating that the pore sizes recited in the instant claims provide unusual results.

Applicants presented no argument regarding the rejection under 35 USC 103(a) but rather indicated that because applicants argued against the rejection under 35 USC 102, the rejection under 35 USC 103(a) should be dropped. This position has been considered but is not persuasive. The rejection under 35 USC 102 is maintained for the reasons given above. Similarly, the rejection under 35 USC 103 is maintained.

6. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal et al. (EP 0 562 864) in view of Suzuki et al. (JP 405163424).

Rosenthal discloses the instant biocompatible product where polyglycolic acid film is an enclosing film. Rosenthal does not disclose polypropylene or polyethylene as the material for the enclosing film. However it is known in the art that polyglycolic acid and polypropylene are all thermoplastic polymer materials (see Suzuki, abstract). Therefore, it would have been

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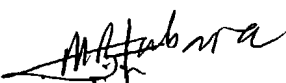
obvious to one of ordinary skill in the art at the time the invention was made to enclose the composition comprising active agents and oxidized regenerated cellulose with a polyglycolic acid film. One having ordinary skill in the art would have been motivated to substitute the polyglycolic acid thermoplastic material with another thermoplastic material such as polypropylene with the expectation that the substitute would effectively enclose the composition for the delivery of the active agent.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Blessing Fubara  
Patent Examiner  
Tech. Center 1600